

Atty's Docket: 101195-67

IN THE CLAIMS

Amend claims as shown below; cancel claims 7-8. Add new claims 11-13.

1 (Currently amended) ~~Method~~ A method for detecting the effect of different chemotherapeutic agents and/or radiation in malignant diseases by determining the expression levels of the p53 gene and/or variants thereof, comprising the steps,

- (a) collecting cells and/or tissue from a subject with a malignant disease,
- (b) determining the expression of the p53 gene or variants thereof by analysis of p53-specific RNA, in a portion of the cells and/or tissue,
- (c) placing into culture an additional portion of the cells and/or tissue, and treating the cultured cells and/or tissue with one or more cytostatic compounds and/or radiation treatments,
- (d) determining the expression profile of the p53 gene or variants thereof, in the cells and/or tissues by analysis of p53-specific RNA, and, assigning an observed change in the treated cells' and /or tissue's expression profile to the corresponding treatment with one or more cytostatic compounds and/or radiation, and
- (e) comparing the expression profile obtained in step (b) with an expression profile of step (d) and based on the comparing, selecting one or more cytostatic compounds and/or radiation treatments for administering to the subject.

wherein the expression profiles of apoptosis-regulating and/or cell-growth-regulating genes and/or individual differences (mutations) in the gene sequences is determined

Atty's Docket: 101195-67

~~and the changes associated with chemotherapeutic agents and/or radiation therapy are identified, represented and diagnostically evaluated.~~

2. (Currently amended) ~~Method A method~~ in accordance with claim 1, wherein the expression profiles of one or more additional genes are determined, the additional genes being selected from the group consisting of the Bcl-2 family, preferably Bax, p53, p16, caspases, Rb, cyclins, inhibitors of cyclin-dependent kinases (CDKs), ATM and inhibitors of apoptosis proteins (IAPs), and/or mutations-variants thereof in the genes are determined using protein or DNA/RNA analyses and evaluated singly or in various combinations.

3. (Currently amended) ~~Method A method~~ in accordance with claim 1, wherein individual differences in the sequence of apoptosis and/or cell growth-regulating genes ~~and and/or the their expression profiles of their gene products, which occur in malignant diseases, are related-correlated with the apoptosis and/or cell growth-regulating genes' to an individually different responsiveness to drugs-cytostatic compounds and/or radiation. and are evaluated, particularly with regard to their relevance to the response to therapy.~~

4. (Currently amended) Method for selecting ~~more efficacious-therapeutic agents for the treatment of malignant diseases, wherein the status-expression profiles of one or more cell cycle genes and/or of apoptosis-associated target genes or of their gene products thereof, in body fluids, cells or organs are determined ex vivo and the more efficacious agents for this status are selected.~~

5. (Currently amended) ~~Method A method~~ in accordance with claim 4, wherein agents

PAGE 4/4 * RCVD AT 10/3/2004 1:27:37 PM [Eastern Daylight Time] * SVR:USPTO-EFRRF-1/0 * DNIS:8729306 * CSID:212 448 9373 * DURATION (mm:ss):01:24,